

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

BRIDGET DOYLE, *et al.*,

Plaintiffs,

v.

BAYER CORPORATION, *et al.*,

Defendants.

Case No. C24-1973-MLP

ORDER

This matter comes before the Court on Defendants Bayer Corporation and Bayer HealthCare Pharmaceuticals Inc.’s (collectively, “Bayer”) Motion to Dismiss (Mot. (dkt. # 16)) Plaintiffs Bridget Doyle and Steve Pearson’s Complaint for damages and demand for jury trial (Compl. (dkt. # 1)). The parties did not seek oral argument with respect to the Motion to Dismiss, and this Court does not find it necessary to its analysis. Having thoroughly considered the briefing and the relevant record, the Court hereby GRANTS Bayer’s Motion for the reasons described below.

I. BACKGROUND

Ms. Doyle and Mr. Pearson’s Complaint alleges the following facts:

1 On July 21, 2010, Ms. Doyle had a Mirena intrauterine device (“IUD”) placed at the
2 University of Washington Medical Center. (Compl. at ¶ 3.2.) Six days later, after Mr. Pearson
3 experienced discomfort during intercourse, they returned to the medical center. (*Id.*) At that time,
4 however, Ms. Doyle and Mr. Pearson decided the issue was not significant enough to remove the
5 IUD. (*Id.*) Two years later, in 2012, Ms. Doyle had an ectopic pregnancy and was informed that
6 her IUD was not in her uterus and had “likely been expelled” from her body. (*Id.* at ¶ 3.3.) More
7 than a decade later, during a visit to The Polyclinic in Seattle for a persistent cough on April 27,
8 2023, an x-ray of Ms. Doyle’s chest revealed a shadow in her abdomen—which doctors
9 suspected to be the IUD. (*Id.* at ¶ 3.4.) On June 7, 2023, Ms. Doyle underwent surgery to remove
10 the IUD. (*Id.* at ¶ 3.5.) Ms. Doyle and Mr. Pearson allege ongoing pain and damages following
11 the surgery. (*Id.* at ¶ 3.6.)

12 On December 1, 2024, Ms. Doyle and Mr. Pearson filed six causes of action against
13 Bayer: (1) strict products liability for failure to warn; (2) strict products liability based on a
14 manufacturing defect; (3) negligence per se; (4) breach of express warranty; (5) breach of
15 implied warranty; and (6) unfair business practices. (Compl. at ¶ 4.1-9.5.)

16 II. DISCUSSION

17 A. Legal Standard

18 To survive a Rule 12(b)(6) motion, “a complaint must contain sufficient factual matter,
19 accepted as true, to state a claim to relief that is plausible on its face.” *Ashcroft v. Iqbal*, 556 U.S.
20 662, 678 (2009) (citation omitted). A claim is facially plausible when the “plaintiff pleads factual
21 content that allows the court to draw the reasonable inference that the defendant is liable for the
22 misconduct alleged.” *Id.* at 678. Although the Court must accept as true a complaint’s
23 well-pleaded facts, “conclusory allegations of law and unwarranted inferences will not defeat an

1 otherwise proper motion to dismiss.” *Vasquez v. Los Angeles Cnty.*, 487 F.3d 1246, 1249 (9th
2 Cir. 2007).

3 A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) may be based on
4 either a lack of a cognizable legal theory or the absence of sufficient facts alleged under such a
5 theory. *Balistreri v. Pacifica Police Dep’t*, 901 F.2d 696, 699 (9th Cir. 1990). The court must
6 accept all facts alleged in the complaint as true and make all inferences in the light most
7 favorable to the non-moving party. *In re Fitness Holdings Int’l, Inc.*, 714 F.3d 1141, 1144-45
8 (9th Cir. 2013).

9 **B. Unopposed Motion**

10 Bayer moves to dismiss Ms. Doyle and Mr. Pearson’s claims, largely on the grounds that
11 these claims are clearly and expressly subsumed by the Washington Products Liability Act
12 (“WPLA”), RCW § 7.72.010, and because Ms. Doyle and Mr. Pearson fail to state any claims
13 upon which relief may be granted. (*See generally* Mot.) Ms. Doyle and Mr. Pearson have not
14 filed a response.

15 Under Local Civil Rule 7(b)(2), “if a party fails to file papers in opposition to a motion,
16 such failure may be considered by the court as an admission that motion has merit.” This applies
17 to the failure to respond to individual claims in a motion to dismiss. *See Leonard v. Recontrust*
18 *Company, N.A.*, 2016 WL 304802, at *8 (W.D. Wash. 2016) (arguments not addressed in
19 opposition to motion to dismiss are waived); *Edwards v. Caliber Home Loans*, 2016 WL
20 9185356, at *2 (W.D. Wash. 2016) (finding that plaintiffs’ failure to respond to portions of
21 defendants’ argument can be construed as conceding that the argument has merit); *Piacentini v.*
22 *U.S.*, 1997 WL 176375, at *2 (W.D. Wash. 1997) (same); *see also Newdow v. Congress of U.S.*
23 *of Am.*, 435 F.Supp. 2d 1066, 1070 n. 5 (E.D. Cal. 2006, *aff’d sub nom.*, *Newdow v. Lefevre*, 598

1 F.3d 638 (9th Cir. 2010) (interpreting plaintiff’s silence as non-opposition to defendant’s motion
2 to dismiss and granting the motion as to the unopposed claims).)

3 The Court considers the non-opposition as an admission that the Motion has merit. As
4 discussed further below, the Court’s own analysis finds that the Motion is meritorious and grants
5 it on that basis as well.

6 **C. WPLA Preemption of First Five Claims**

7 Bayer argues the claims brought by Ms. Doyle and Mr. Pearson are preempted by the
8 WPLA. (Mot. at 15-17.) The WPLA governs all claims for product-related harm in Washington.
9 RCW 7.72.010(4); *see, e.g., Crittenden v. Fibreboard Corp.*, 58 Wn. App. 649, 656 n. 9 (Wash.
10 Ct. App. 1990) (there is a “single product liability claim” in Washington); *Wash. Water Power*
11 *Co. v. Graybar Elec. Co.*, 112 Wn.2d 847, 855 n. 4 (Wash. 1989) (the “WPLA preempts the
12 variety of common law causes of action for harm caused by product defects”). Since Ms. Doyle
13 and Mr. Pearson’s first five causes of action are subsumed under the WPLA and they have not
14 specifically alleged a claim under this statute, dismissal is warranted. The WPLA does not
15 preempt Ms. Doyle and Mr. Pearson’s sixth cause of action, however, which comes under the
16 Washington Consumer Protection Act (“WCPA”). *See Hoefs v. Sig Sauer Inc.*, 2020 WL
17 3488155, at *2 (W.D. Wash. June 26, 2020).

18 **D. Federal Preemption of WCPA Claim**

19 Ms. Doyle and Mr. Pearson generally allege that Bayer failed to adequately warn of the
20 risks associated with the IUD. (*See generally* Compl.) Bayer responds that Ms. Doyle and Mr.
21 Pearson’s claims are preempted by the federal Food, Drug, and Cosmetic Act (“FDCA”). (Mot.
22 at 17-18.) The crux of Bayer’s argument is that even if it wanted to change the IUD’s label in the
23 manner Ms. Doyle and Mr. Pearson suggest, it was prohibited from doing so under federal law.

(*Id.*) Under the Food and Drug Administration’s (“FDA”) “changes being effected” (“CBE”) regulation, manufacturers are allowed to make certain label changes based on “newly acquired information” that strengthens a warning if there is evidence of a causal association of risk. *Mahnke v. Bayer Corp.*, 2020 WL 2048622, at *3 (C.D. Cal. Mar. 10, 2020) (citing *Merck Sharp & Dahme Corp. v. Albrecht*, 587 U.S. 299 (2019)). “Newly acquired information” refers to data or analyses not previously submitted to the FDA. *Holley v. Gilead Scis., Inc.*, 379 F.Supp. 3d 809, 830 (N.D. Cal. 2019) (citing 21 C.F.R. § 341.3(b)).

To avoid federal preemption, Ms. Doyle and Mr. Pearson must plead a label deficiency that Bayer could have corrected using the CBE regulation. *See Mahnke*, at *3. “Stated differently, [Ms. Doyle and Mr. Pearson] must allege facts showing that Bayer could have unilaterally changed [the IUD’s] label under the CBE regulation because Bayer had (or should have had) newly acquired information about evidence of a causal association between [the IUD] and a clinically significant adverse reaction.” *Id.* (citing *Klein v. Bayer Healthcare Pharm. Inc.*, 2019 WL 3945652, at *5 (D. Nev. Aug. 21, 2019); *Albrecht*, 587 U.S. at 304-05). In this case, Ms. Doyle and Mr. Pearson have not alleged any newly acquired information or undisclosed risk that connects the dots between the IUD and a clinically significant adverse reaction in patients. (*See generally* Compl.; *but see* Mot. at 12-14, Ex. A.¹) Accordingly, Ms. Doyle and Mr. Pearson’s failure-to-warn-based claims are preempted.

¹ Bayer asserts that Exhibit A is subject to judicial notice and incorporated by reference. (Mot. at 12-13.) Exhibit A is a public FDA document containing prescribing information for the IUD that Ms. Doyle and Mr. Pearson’s claims are based on. The existence and content of the FDA document is not subject to reasonable dispute and is therefore subject to judicial notice, *see* Fed. R. Evid. 201(b)(1)-(2), as well as incorporation by reference, as Ms. Doyle and Mr. Pearson’s claims are based on Bayer’s alleged lack of warning, including in FDA materials. *See Eidmann v. Walgreen Co.*, 522 F.Supp.3d 634, 642 (N.D. Cal. 2021) (“Documents published on government-run websites are proper for judicial notice given their reliability.”).

1 **E. Failure to State a Claim**

2 Bayer also contends that all of Ms. Doyle and Mr. Pearson’s claims should be dismissed
3 for failure to allege facts sufficient to state a plausible claim for relief. (Mot. at 11, 20-29.)

4 **a. Plaintiffs Failed to State a Failure to Warn Claim**

5 Ms. Doyle and Mr. Pearson’s first cause of action asserts that Bayer is strictly liable for
6 failing to adequately warn about the potential side effects of the IUD, such as perforation and
7 migration within the body. (Compl. at ¶ 4.1-4.8.) Bayer argues for dismissal because the claim
8 does not adequately detail any nonexistent or inadequate warning and is contrary to
9 Washington’s learned intermediary doctrine. (Mot. at 20-25.)

10 Where plaintiffs allege that a manufacturer provided inadequate warnings, they must
11 show that the injury was proximately caused by a product deemed unreasonably unsafe due to
12 the manufacturer’s failure to provide adequate warnings or instructions. *See Ayers v. Johnson &*
13 *Johnson Baby Prods. Co.*, 117 Wn.2d 747, 752 (Wash. 1991). In this context, Ms. Doyle and Mr.
14 Pearson’s claims rely on risks that were already disclosed in the FDA-approved IUD prescribing
15 information, as noted above. (*See generally* Compl.; *but see* Mot. at 12-14, Ex. A.) Ms. Doyle
16 and Mr. Pearson do not provide any facts showing that these warnings were insufficient. As
17 such, Ms. Doyle and Mr. Pearson’s failure to warn claim is legally unsustainable. *See Alvarez v.*
18 *Bayer US, Inc.*, 2021 WL 8742153, at *3 (C.D. Cal. Dec. 15, 2021) (dismissing failure to warn
19 claim because “Plaintiff pleaded merely conclusory allegations.”).

20 Ms. Doyle and Mr. Pearson’s claim is also precluded by Washington’s learned
21 intermediary doctrine, which requires drug companies to provide warnings to the prescribing
22 physicians rather than directly to patients. *Wash. St. Physicians Ins. Exch. & Ass’n v. Fisons*
23 *Corp.*, 122 Wn.2d 299, 312-14 (Wash. 1993). “In order to prove causation, a plaintiff must allege

1 that the inadequate warning or lack of warning about the medical device risk would have altered
2 the prescribing physician's decision to use the product." *Andren v. Alere, Inc.*, 207 F.Supp. 3d
3 1133, 1144 (S.D. Cal. Sept. 13, 2016). Here, Ms. Doyle and Mr. Pearson have not asserted that
4 Bayer failed to warn Ms. Doyle's physician or that adequate warnings would have changed the
5 physician's decision to use the IUD. (*See, e.g.*, Compl. at ¶ 3.3 (the "IUD manufactured by Bayer
6 was recommended as a safe, uncomplicated and effective birth control device.").)

7 Accordingly, Ms. Doyle and Mr. Pearson's failure to warn claim is dismissed with
8 prejudice because, based on the above reasoning, amendment would be futile. *See United States*
9 *v. Corinthian Colleges*, 655 F.3d 984, 995 (9th Cir. 2011).

10 **b. Plaintiffs Failed to State a Manufacturing Defect Claim**

11 Ms. Doyle and Mr. Pearson's second cause of action asserts that Bayer distributed an
12 IUD with a manufacturing defect, rendering it unsuitable for its intended use. (Compl. at
13 ¶ 5.1-5.5.) To succeed on a manufacturing defect claim, a plaintiff must demonstrate that the
14 product deviated materially from the manufacturer's design specifications or the performance
15 standards applicable to similar products when it left the manufacturer's control and that this
16 deviation proximately caused plaintiff's harm. *Staub v. Zimmer, Inc.*, 2017 WL 2506166, at *4
17 (W.D. Wash. June 9, 2017) (citing RCW 7.72.030(2)(a)). Bayer seeks dismissal of this claim on
18 the basis that Ms. Doyle and Mr. Pearson's complaint lacks specific allegations detailing any
19 manufacturing defect. (Mot. at 25-26.) The Court agrees, as the complaint does not specify how
20 the IUD deviated from its design or performance standards or what specific aspect of the product
21 posed a danger. Instead, the complaint simply states that the IUD was defective and dangerous.
22 (Compl. at ¶ 5.3, 5.5.) Such conclusory allegations are insufficient to state a claim under *Iqbal*.
23 556 U.S. at 680. Accordingly, Ms. Doyle and Mr. Pearson's manufacturing defect claim is

1 dismissed with prejudice, as “[a]mendment is futile when a plaintiff’s claims are based on
2 threadbare allegations and legal conclusions, the plaintiff fails to rebut any of the defendant’s
3 arguments in the motion to dismiss, and there is an applicable defense to the claim plaintiff
4 alleges.” *Leavitt v. Credit Central, LLC*, 2024 WL 4839360, at *2 (W.D. Wash. Nov. 20, 2024)
5 (citing *Aguiar v. Cal. Sierra Express, Inc.*, 2012 WL 1593202, at *2 (E.D. Cal. May 4, 2012).

6 **c. Plaintiffs Failed to State a Negligence *per se* Claim**

7 Ms. Doyle and Mr. Pearson allege that Bayer breached their duty to them by failing to
8 meet the standard of care set by the FDCA and RCW 19.28.371, making Bayer negligent *per se*.
9 (Compl. at ¶ 6.1-6.6.) Although violations of statutes or duties may serve as evidence of
10 negligence, they cannot form the basis for a separate cause of action. *In re MCG Health Data*
11 *Sec. Issue Litig.*, 2023 WL 3057428, at *2-3 (W.D. Wash. Mar. 27, 2023). Accordingly, Ms.
12 Doyle and Mr. Pearson’s negligence *per se* claim is dismissed with prejudice. *See Leavitt*, at *2.

13 **d. Plaintiffs Failed to State a Breach of Express Warranty Claim**

14 To state a claim for express warranty under the WPLA, Ms. Doyle and Mr. Pearson must
15 demonstrate that (1) Bayer made a warranty as part of the basis of the bargain; (2) the warranty
16 concerns a material fact about the product; and (3) the warranty was breached. *Bryant v. Wyeth*,
17 879 F.Supp.2d 1214, 1226 (W.D. Wash. 2012) (defining express warranty as an “affirmation of
18 fact or promise”). Here, Ms. Doyle and Mr. Pearson allege only that Bayer “expressly
19 warranted” that the device “would be safe and effective,” and then claim a breach because the
20 device had “harmful and serious side effects.” (Compl. at ¶ 7.1-7.4.) However, Ms. Doyle and
21 Mr. Pearson fail to specify what specific representations or warranties were made, when or
22 where, or how they relied on them. These types of conclusory allegations fall short of the
23 pleading standards necessary to sustain Ms. Doyle and Mr. Pearson’s claims. *See Afoa v. China*

1 *Airlines Ltd.*, 2013 WL 3354388, at *2-3 (W.D. Wash. July 3, 2013). Accordingly, Ms. Doyle
2 and Mr. Pearson’s express warranty claim is dismissed with prejudice. *See Leavitt*, at *2.

3 **e. Plaintiffs Failed to State a Breach of Implied Warranty Claim**

4 Ms. Doyle and Mr. Pearson’s claim for breach of implied warranty also fails due to
5 insufficient factual allegations. “Generally, contractual privity between the buyer and seller must
6 exist before a plaintiff may maintain an action for a breach of warranty.” *Thongchoom v. Graco*
7 *Children’s Prod., Inc.*, 117 Wn. App. 299, 307 (Wash. Ct. App. 2003). Washington courts apply
8 the “sum of the interaction” test to determine whether a manufacturer was sufficiently involved
9 in a transaction (including post-sale) with a remote purchaser to warrant enforcement of an
10 implied warranty. *See, e.g., Touchet Valley Grain Growers, Inc. v. Opp & Siebold General*
11 *Constr. Inc.*, 119 Wn.2d 334, 345-47 (Wash. 1992).

12 Ms. Doyle and Mr. Pearson do not allege that Bayer knew of them, in particular, or that
13 the IUD was designed to their particular specifications. Nor do they claim that Bayer delivered
14 the IUD to them, rather than the hospitals or doctors who directly purchased the IUD, or that
15 Bayer joined in the attempts to alleviate their symptoms or dispatched anyone to assist. (*See*
16 *generally* Compl.) In short, Ms. Doyle and Mr. Pearson fail to provide plausible factual
17 allegations to support their legal conclusion that they were the intended third-party beneficiaries
18 of the contract between physicians or providers and Bayer. *See Harju v. Johnson & Johnson*,
19 2021 WL 5182057, at *9 (W.D. Wash. July 12, 2021) (dismissing implied warranty claim
20 alleging that implanted medical device was neither merchantable nor suited for its intended use
21 as warranted). Accordingly, Ms. Doyle and Mr. Pearson’s implied warranty claim is dismissed
22 with prejudice. *See Leavitt*, at *2.

f. Plaintiffs Failed to State an Unfair Business Practices Claim

Ms. Doyle and Mr. Pearson's claim under the WCPA is facially deficient because it relies on damages stemming from physical injury and emotional distress, which are not recoverable under the WCPA. To state a WCPA claim under Washington law, a private plaintiff must prove: (1) an unfair or deceptive act or practice; (2) in trade or commerce; (3) affecting the public interest; (4) caused injury to the plaintiff's business or property; and (5) that the injury was caused by the unfair practice. *See Brotherson v. Prof'l Basketball Club, L.L.C.*, 604 F.Supp. 2d 1276, 1294 (W.D. Wash. 2009). Physical injuries and emotional distress are excluded from damages recoverable under the WCPA. *Id.* As Ms. Doyle and Mr. Pearson's injuries stem from physical injuries rather than an unfair business practice caused by Bayer (*see* Compl. at ¶ 9.5, 10.2-10.6), their WCPA claim fails. Accordingly, Ms. Doyle and Mr. Pearson's WCPA claim is dismissed with prejudice. *See Corinthian Colleges*, at 995.

g. Plaintiffs Failed to State a Loss of Consortium Claim

Courts have consistently held that generic assertions that the plaintiff is the spouse of the injured person are insufficient to state a loss of consortium claim. *See, e.g., Butler v. Ethicon, Inc.*, 2021 WL 6137348, at *3 (E.D. Wash. Mar. 25, 2021). Ms. Doyle and Mr. Pearson have not pleaded any facts supporting that Mr. Pearson experienced a loss in love, companionship, or services resulting from Ms. Doyle's injury beyond mere status as her spouse. (*See* Compl. at ¶ 10.6.) Moreover, as their predicate causes of action are dismissed, their loss-of-consortium claim *a fortiori* fails, because such claims cannot independently stand. *See Carter v. Ethicon Inc.*, 2021 WL 1893749, slip op. at 3 (W.D. Wash. 2021). Accordingly, Ms. Doyle and Mr. Pearson's loss of consortium claim is dismissed with prejudice. *See Leavitt*, at *2.

F. Statute of Limitations

Bayer contends that even if Ms. Doyle and Mr. Pearson had presented sufficient facts to establish a claim under the WPLA, it would be time barred. (Mot. at 29-31.) Since the Court concludes that Ms. Doyle and Mr. Pearson's claims are preempted by federal and state law, their non-opposition is an admission of the Motion's merit, and the complaint failed to meet the required level of particularity, the Court does not reach Bayer's alternative argument that Ms. Doyle and Mr. Pearson failed to bring their claims within the statute of limitations period.

III. CONCLUSION

For the foregoing reasons, Bayer's Motion (dkt. # 16) is GRANTED and Ms. Doyle and Mr. Pearson's Complaint (dkt. # 1) is DISMISSED with prejudice.

Dated this 12th day of June, 2025.

M. J. Peterson

MICHELLE L. PETERSON
United States Magistrate Judge